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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,497	08/15/2006	Isao Miyagawa	0033-1091PUS1	9861

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
JANSSEN, SHANNON L	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/589,497	MIYAGAWA ET AL.	
	Examiner	Art Unit	
	SHANNON JANSSEN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 22, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are currently pending. Claims 4-5 have been withdrawn and claims 6-8 were added in the claim amendments received October 22, 2009. Claims 1-3 and 6-8 are currently under consideration.

Election/Restrictions

Applicant's elected Group I (claims 1-3) in the reply filed on July 29, 2009 **without** traverse.

Claims 4-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions, there being no allowable generic or linking claim.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on March 3, 2004. The office is being requested to retrieve the document.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 15, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Invention as Claimed

One embodiment of the present invention is drawn to a method comprising contacting a solution comprising a sample biopolymer with only a glass slide, wherein a probe biopolymer is immobilized to the glass slide, placing the glass slide into a vessel comprising a solution having the same vapor pressure as the solution comprising the sample biopolymer, wherein the vessel

solution is not in contact with the solution comprising the sample biopolymer, closing the vessel, and hybridizing the sample biopolymer and the probe biopolymer.

Withdrawn rejections

The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants claim amendments.

The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Clontech (GlassHyb ® Hybridization solution user manual, published January 9, 2001) is withdrawn in view of applicants claim amendments.

The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Schembri (US Patent Application Publication 2001/0046702, filed June 19, 2001) is withdrawn in view of applicants claim amendments.

The rejection of Claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Clontech GlassHyb ® Hybridization solution user manual, published January 9, 2001) and Sato et al (US Patent Application Publication 2002/0127589, published September 12, 2002, provided by applicants in IDS)) is withdrawn in view of applicants claim amendments.

The rejection of Claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Schembri (US Patent Application Publication 2001/0046702, filed June 19, 2001) and Sato et al (US Patent Application Publication 2002/0127589, published September 12, 2002, provided by applicants in IDS) is withdrawn in view of applicants claim amendments.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyman et al. (US Patent Number 6555361, granted April 29, 2003), Suzuki et al. (Non-isotopic in situ hybridization of CD44 transcript in formalin-fixed paraffin-embedded sections, Brain Research Protocols, 1999, vol 4, pp 29-35), Morel et al. (In situ Hybridization in electron microscopy, 2001, CRC Press, Boca Raton, Section 6.9: Hybridization, pp 1-2 and 239-243), and Sato et al (US Patent Application Publication 2002/0127589, published September 12, 2002, provided by applicants in IDS).

Regarding present claims 1 and 6-8, Lyman et al. teach a method of hybridizing a sample to a probe on a glass slide comprising contacting a solution comprising the sample to be tested (i.e.: sample biopolymer, such as DNA since the probe is DNA) to a glass slide that has DNA sequences immobilized on the surface (i.e.: probe biopolymer) wherein the test sample is applied to the glass slide only (e.g.: the coverslip is not placed on the slide until afterward the sample has been added, since the limitation that the coverslip is not required for the hybridization step in the vessel), placing the glass slide in a hybridization chamber containing a liquid to prevent evaporation and keep the chamber humidified, wherein the liquid in the hybridization chamber is not in contact with the solution on the slide containing the sample, sealing the vessel, and hybridizing the sample and the probe (See entire document, particularly Abstract and cols 3-4). It

is noted that Lyman et al. do not specifically teach wherein the volume of the solution in the chamber is 5 times the volume of the solution comprising the sample, however, Lyman et al. do teach wherein the sample solution is only 5 microliters and the wells containing the chamber solution can hold 18 microliters, and wherein there can be any number of wells so that the cumulative volume would be sufficient to saturate the environment (see col 3).

While Lyman et al. teach a method of hybridizing a sample and probe biopolymer in a sealed chamber containing a fluid to maintain humidity and prevent evaporation of the sample solution from the slide, Lyman et al. do not specifically teach wherein the solution contained in the chamber and the solution comprising the sample have the same vapor pressure.

Regarding present claims 1 and 6-8, Suzuki et al. teach a method of hybridizing a sample to a probe on a glass slide comprising contacting a solution comprising the sample to be tested (i.e.: sample biopolymer) to a glass slide that has DNA sequences immobilized on the surface (i.e.: probe biopolymer) and placing the slide in a chamber comprising paper towels soaked in a 50% Formamide solution (i.e.: the amount of solution in the paper towels would necessarily be at least 5 times the quantity of the solution comprising the sample biopolymer), closing the container, and hybridizing the sample and probe (See particularly p 31). Suzuki et al. further state, regarding the use of the soaked paper towels:

"By this procedure, there is no need for covering the sections with coverslips or sheets of parafilm, if the moist chamber is sufficiently air tight" (See p 31).

While Lyman et al. and Suzuki et al. teach a chamber solution having a composition similar to the solution comprising the sample, Lyman et al. in combination with Suzuki et al. do

not specifically teach wherein the solution contained in the chamber and the solution comprising the sample have the same vapor pressure.

Regarding present claim 1, Morel et al. teach a hybridization method comprising a sample solution that is essentially the same as the chamber solution (i.e.: have approximately the same vapor pressure; see p 241, where it states that the 4X SSC is the only essential component for the hybridization, e.g. sample biopolymer, buffer, and p 242, where it states that the paper towels are soaked in 5X SSC).

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). **MPEP 2144.05**

Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). **MPEP 2144.05**

While Lyman et al. in combination with Suzuki et al. and Morel et al. teach a method of hybridizing a sample and probe biopolymer in a sealed chamber containing a fluid with the same vapor pressure as the fluid containing the sample to maintain humidity and prevent evaporation of the sample solution from the slide, Lyman et al. in combination with Suzuki et al. and Morel et al. do not teach a slide glass comprising hydrophilic and hydrophobic regions.

Regarding present claims 2-3 Sato et al. teaches a hybridization microarray comprising a hydrophilic region to which probe biopolymers are fixed and a hydrophobic region to which no probe biopolymer is immobilized formed around the arranged plurality of hydrophilic regions (Abstract, [0011, 0021-0023]).

Therefore one of skill in the art at the time of the invention would have had a reasonable expectation for success in modifying Lyman et al. with Suzuki et al, Morel et al., and Sato et al. because Lyman et al., Suzuki et al., and Morel et al. are all directed to similar methods of hybridizing a sample to a glass slide comprising an immobilized probe, using humidified closed chambers to prevent evaporation of the solution comprising the sample, and using a variety of solution compositions which can be optimized. One would have had a reasonable expectation for success in using the glass slide taught by Sato et al. because all of the cited references utilized glass slides.

One would have been motivated to modify Lyman et al. with Suzuki et al., Morel et al., and Sato et al. because Suzuki et al. teach the advantage of using a solution that keeps the chamber humidified (e.g.: cover slips are not required) and Lyman et al. teach that the method can be modified (in that certain components are indespensible while others are useful or optional). Further, Sato et al. teach the advantage of using an array with hydrophilic and hydrophobic regions as being advantageous because it is "capable of shaping a spot of probe DNA to be fixed, into the desired shape readily and easily" (specification, [0010-0011]).

Therefore the teachings of Lyman et al., Suzuki et al., Morel et al., and Sato et al. renders the present invention *prima facie* obvious.

In addition, it would have been obvious to substitute known elements (i.e.: the different chamber solution for preventing evaporation as taught by Lyman et al., Suzuki et al., and Morel et al.) because the substitution would have yielded the predictable result of keeping the chamber humidified to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, USPQ2d 1385 (U.S. 2007).

Response to Arguments

Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection. In addition, applicants did not argue that the Sato et al. reference did not meet the limitations of claims 2-3, applicants only argued with regard to amended claim 1.

Future Communications

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shannon L Janssen

SLJ

/JEFFREY S. LUNDGREN/
Primary Examiner, Art Unit 1639